

Version: Jun2013

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Page: 4

Report Date: 06/17/2013

Study Summary

| Laboratory Name | Study Number | Study Start Date | Length of Study in Days | Number of Animals Total and (#/Cage) | Number Surviving and (Mean Life Span) | Maximum Mean Weekly Body Weight | Chemical |
|------------------------------|--------------|------------------|-------------------------|--------------------------------------|---------------------------------------|---------------------------------|--------------------------|
| Male | | | | | | | |
| Battelle Columbus Laboratory | 052000603 | 03/14/07 | 727 | 50(3) | 20(644) | 584.8 | Indole-3-carbinol |
| Battelle Columbus Laboratory | 052030401 | N/A | N/A | 0(0) | 0(0) | N/A | TEF evaluation (PCB 118) |
| Female | | | | | | | |
| Battelle Columbus Laboratory | 052000603 | 03/15/07 | 729 | 50(5) | 21(637) | 353.0 | Indole-3-carbinol |
| Battelle Columbus Laboratory | 052030401 | 03/26/04 | 733 | 52(5) | 21(616) | 383.5 | TEF evaluation (PCB 118) |

NOTE: The text on page 2 ("Report Description") describes how the studies listed here are displayed on the data pages that follow.

| | | Male | | | Female | | |
|--------------------------------------|-------|-------------|----------|-------|-----------------------|-------------|----------|
| #All Organs: | | | | | | | |
| Benign Tumors | | | | | | | |
| | | 27/50 (54%) | | | 40/50 (80%) | 43/52 (83%) | |
| Overall Incidence | Total | 27/50 (54%) | Mean 54% | SD 0% | Total 83/102 (81.37%) | Mean 81.35% | SD 1.9% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant Tumors | | | | | | | |
| | | 12/50 (24%) | | | 14/50 (28%) | 15/52 (29%) | |
| Overall Incidence | Total | 12/50 (24%) | Mean 24% | SD 0% | Total 29/102 (28.43%) | Mean 28.42% | SD 0.6% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Malignant and Benign Tumors | | | | | | | |
| | | 33/50 (66%) | | | 46/50 (92%) | 48/52 (92%) | |
| Overall Incidence | Total | 33/50 (66%) | Mean 66% | SD 0% | Total 94/102 (92.16%) | Mean 92.15% | SD 0.22% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | 1/52 (2%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Hemangiosarcoma or Hemangioma | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | 1/52 (2%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | |
| #All Organs: | | | | | | | |
| Histiocytic Sarcoma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 1/52 (2%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 2/102 (1.96%) | Mean 1.96% | SD 0.05% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | Male | | | | Female | | | |
|--|-------|------------|----------|-------|-----------|---------------|------------|----------|
| #All Organs: | | | | | | | | |
| Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | 2/52 (4%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.92% | SD 2.72% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Benign, Malignant, NOS | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #All Organs: | | | | | | | | |
| Mesothelioma: Malignant | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | 2/52 (4%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.92% | SD 2.72% |
| | | | | | | | | |
| *Adrenal Cortex: | | | | | | | | |
| Carcinoma | | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | 1/52 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | |
| *Adrenal Medulla: | | | | | | | | |
| Pheochromocytoma Benign | | | | | | | | |
| | | 5/50 (10%) | | | 0/50 (0%) | 3/52 (6%) | | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total | 3/102 (2.94%) | Mean 2.88% | SD 4.08% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | | Male | | | Female | | |
|--|-------|------------|----------|-------|-----------|---------------|---------------------|
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Complex | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma Malignant | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/102 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Adrenal Medulla: | | | | | | | |
| Pheochromocytoma: Benign, Complex, Malignant, NOS | | | | | | | |
| | | 8/50 (16%) | | | 0/50 (0%) | 3/52 (6%) | |
| Overall Incidence | Total | 8/50 (16%) | Mean 16% | SD 0% | Total | 3/102 (2.94%) | Mean 2.88% SD 4.08% |
| | | | | | | | |
| *Brain: | | | | | | | |
| Granular Cell Tumor Benign | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 0/52 (0%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/102 (0.98%) | Mean 1% SD 1.41% |
| | | | | | | | |
| *Heart: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Islets, Pancreatic: | | | | | | | |
| Adenoma | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/102 (0%) | Mean 0% SD 0% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/17/2013

| | | Male | | | | Female | | | |
|---|-------|------|------|---------|-------|--------|---------|------------|----------|
| *Islets, Pancreatic: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 2/50 | (4%) | | | 0/50 | (0%) | 0/52 | (0%) |
| Overall Incidence | Total | 2/50 | (4%) | Mean 4% | SD 0% | 0/102 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | 0/52 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | 0/102 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Kidney: Renal Tubule: | | | | | | | | | |
| Carcinoma or Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | 0/52 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | 0/102 | (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Cholangioma | | | | | | | | | |
| | | 0/50 | (0%) | | | 0/50 | (0%) | 1/52 | (2%) |
| Overall Incidence | Total | 0/50 | (0%) | Mean 0% | SD 0% | 1/102 | (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 2/50 | (4%) | 0/52 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | 2/102 | (1.96%) | Mean 2% | SD 2.83% |
| | | | | | | | | | |
| *Liver: | | | | | | | | | |
| Hepatocellular Carcinoma or Hepatocellular Adenoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 2/50 | (4%) | 0/52 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | 2/102 | (1.96%) | Mean 2% | SD 2.83% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: Jun2013
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Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
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| | Male | | | | Female | | | |
|--|-------|-----------|---------|-------|-----------|---------------|---------|----------|
| *Liver: | | | | | | | | |
| Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma | | | | | | | | |
| | | 1/50 (2%) | | | 2/50 (4%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 2/102 (1.96%) | Mean 2% | SD 2.83% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 0/49 (0%) | | | 1/50 (2%) | 0/51 (0%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 1/101 (0.99%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma | | | | | | | | |
| | | 0/49 (0%) | | | 1/50 (2%) | 0/51 (0%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 1/101 (0.99%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| *Lung: | | | | | | | | |
| Sarcoma | | | | | | | | |
| | | 0/49 (0%) | | | 1/50 (2%) | 0/51 (0%) | | |
| Overall Incidence | Total | 0/49 (0%) | Mean 0% | SD 0% | Total | 1/101 (0.99%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| #Lymph Node, Mesenteric: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Mammary Gland: | | | | | | | | |
| Adenoma | | | | | | | | |
| | | 0/50 (0%) | | | 3/50 (6%) | 0/52 (0%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 3/102 (2.94%) | Mean 3% | SD 4.24% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

| | | Male | | | Female | | |
|---|-------|-----------|---------|-------|-----------------------|-------------|----------|
| #Mammary Gland: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 3/50 (6%) | 2/52 (4%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 5/102 (4.9%) | Mean 4.92% | SD 1.52% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 6/50 (12%) | 2/52 (4%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 8/102 (7.84%) | Mean 7.92% | SD 5.77% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Fibroadenoma | | | | | | | |
| | | 1/50 (2%) | | | 29/50 (58%) | 25/52 (48%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 54/102 (52.94%) | Mean 53.04% | SD 7.02% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma or Adenoma | | | | | | | |
| | | 1/50 (2%) | | | 30/50 (60%) | 25/52 (48%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 55/102 (53.92%) | Mean 54.04% | SD 8.43% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Fibroma, Fibroadenoma, Carcinoma, or Adenoma | | | | | | | |
| | | 1/50 (2%) | | | 32/50 (64%) | 27/52 (52%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 59/102 (57.84%) | Mean 57.96% | SD 8.54% |
| | | | | | | | |
| #Mammary Gland: | | | | | | | |
| Myoepithelioma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 0/52 (0%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|-----------|---------------|------------|----------|
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Oral Mucosa: Squamous Cell Carcinoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| *Ovary: Granulosa-Theca Tumor Benign | | | | | | | | |
| | | | | | 1/50 (2%) | 0/52 (0%) | | |
| Overall Incidence | | | | | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| *Ovary: Luteoma | | | | | | | | |
| | | | | | 0/50 (0%) | 1/52 (2%) | | |
| Overall Incidence | | | | | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | |
| *Ovary: Tubulostromal Carcinoma | | | | | | | | |
| | | | | | 1/50 (2%) | 0/52 (0%) | | |
| Overall Incidence | | | | | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | | Male | | | Female | | |
|---|-------|------------|----------|-------|-----------------------|-------------|----------|
| *Pancreas: | | | | | | | |
| Adenoma | | | | | | | |
| | | 5/50 (10%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Pancreas: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 5/50 (10%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Adenoma | | | | | | | |
| | | 5/50 (10%) | | | 18/50 (36%) | 17/52 (33%) | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total 35/102 (34.31%) | Mean 34.35% | SD 2.34% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | 2/52 (4%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 2/102 (1.96%) | Mean 1.92% | SD 2.72% |
| | | | | | | | |
| *Pituitary Gland: Pars Distalis or Unspecified Site: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 5/50 (10%) | | | 18/50 (36%) | 19/52 (37%) | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total 37/102 (36.27%) | Mean 36.27% | SD 0.38% |
| | | | | | | | |
| *Salivary Glands: | | | | | | | |
| Schwannoma Malignant | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/51 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 0/101 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | | Male | | | Female | | |
|---|-------|------------|----------|-------|---------------------|------------|----------|
| #Skeletal Muscle: | | | | | | | |
| Sarcoma | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 0/52 (0%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Basal Cell Carcinoma | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma | | | | | | | |
| | | 6/50 (12%) | | | 0/50 (0%) | 1/52 (2%) | |
| Overall Incidence | Total | 6/50 (12%) | Mean 12% | SD 0% | Total 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | |
| #Skin: | | | | | | | |
| Fibroma | | | | | | | |
| | | 5/50 (10%) | | | 1/50 (2%) | 2/52 (4%) | |
| Overall Incidence | Total | 5/50 (10%) | Mean 10% | SD 0% | Total 3/102 (2.94%) | Mean 2.92% | SD 1.31% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | Male | | | | Female | | | |
|---|-------|------------|----------|-------|-----------|---------------|------------|----------|
| #Skin: | | | | | | | | |
| Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 7/50 (14%) | | | 2/50 (4%) | 2/52 (4%) | | |
| Overall Incidence | Total | 7/50 (14%) | Mean 14% | SD 0% | Total | 4/102 (3.92%) | Mean 3.92% | SD 0.11% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma | | | | | | | | |
| | | 1/50 (2%) | | | 1/50 (2%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma | | | | | | | | |
| | | 2/50 (4%) | | | 1/50 (2%) | 0/52 (0%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Fibrous Histiocytoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Hemangiosarcoma | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 1/52 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Keratoacanthoma | | | | | | | | |
| | | 4/50 (8%) | | | 0/50 (0%) | 1/52 (2%) | | |
| Overall Incidence | Total | 4/50 (8%) | Mean 8% | SD 0% | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: Harlan Sprague-Dawley
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: GAVAGE
 Vehicle: CORN OIL

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 Report Date: 06/17/2013

| | Male | | | | Female | | | |
|---|-------|-----------|---------|-------|-----------|---------------|------------|----------|
| #Skin: | | | | | | | | |
| Neurofibrosarcoma or Schwannoma (malignant or NOS) | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 1/52 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 1/52 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Schwannoma Malignant | | | | | | | | |
| | | 0/50 (0%) | | | 1/50 (2%) | 1/52 (2%) | | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/102 (1.96%) | Mean 1.96% | SD 0.05% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma | | | | | | | | |
| | | 2/50 (4%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 2/50 (4%) | Mean 4% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | |
| #Skin: | | | | | | | | |
| Squamous Cell Papilloma | | | | | | | | |
| | | 1/50 (2%) | | | 0/50 (0%) | 0/52 (0%) | | |
| Overall Incidence | Total | 1/50 (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

| | Male | | | | Female | | | | |
|---|-------|------|---------|------------|--------|-------|---------------|------------|----------|
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma or Papilloma | | | | | | | | | |
| | | 1/50 | (2%) | | | 0/50 | (0%) | 0/52 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 0/102 (0%) | Mean 0% | SD 0% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma | | | | | | | | | |
| | | 5/50 | (10%) | | | 0/50 | (0%) | 1/52 | (2%) |
| Overall Incidence | Total | 5/50 | (10%) | Mean 10% | SD 0% | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | | |
| #Skin: | | | | | | | | | |
| Squamous Cell Papilloma, Papilloma, or Keratoacanthoma | | | | | | | | | |
| | | 5/50 | (10%) | | | 0/50 | (0%) | 1/52 | (2%) |
| Overall Incidence | Total | 5/50 | (10%) | Mean 10% | SD 0% | Total | 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma | | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | 0/52 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | | |
| #Stomach, Forestomach: | | | | | | | | | |
| Squamous Cell Carcinoma or Papilloma Squamous | | | | | | | | | |
| | | 1/50 | (2%) | | | 1/50 | (2%) | 0/52 | (0%) |
| Overall Incidence | Total | 1/50 | (2%) | Mean 2% | SD 0% | Total | 1/102 (0.98%) | Mean 1% | SD 1.41% |
| | | | | | | | | | |
| *Testes: | | | | | | | | | |
| Adenoma | | | | | | | | | |
| | | 3/49 | (6%) | | | | | | |
| Overall Incidence | Total | 3/49 | (6.12%) | Mean 6.12% | SD 0% | | | | |
| | | | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | | Male | | | Female | | |
|---|-------|--------------|------------|-------|-------------|--------------|----------------------|
| *Thymus: | | | | | | | |
| Thymoma Benign | | | | | | | |
| | | 1/46 (2%) | | | 0/47 (0%) | 0/51 (0%) | |
| Overall Incidence | Total | 1/46 (2.17%) | Mean 2.17% | SD 0% | Total | 0/98 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thymus: | | | | | | | |
| Thymoma: Benign, Malignant, NOS | | | | | | | |
| | | 1/46 (2%) | | | 0/47 (0%) | 0/51 (0%) | |
| Overall Incidence | Total | 1/46 (2.17%) | Mean 2.17% | SD 0% | Total | 0/98 (0%) | Mean 0% SD 0% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Adenoma | | | | | | | |
| | | 13/50 (26%) | | | 11/49 (22%) | 9/51 (18%) | |
| Overall Incidence | Total | 13/50 (26%) | Mean 26% | SD 0% | Total | 20/100 (20%) | Mean 20.05% SD 3.4% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | 2/51 (4%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 2/100 (2%) | Mean 1.96% SD 2.77% |
| | | | | | | | |
| *Thyroid Gland: C-Cell: | | | | | | | |
| Carcinoma or Adenoma | | | | | | | |
| | | 13/50 (26%) | | | 11/49 (22%) | 11/51 (22%) | |
| Overall Incidence | Total | 13/50 (26%) | Mean 26% | SD 0% | Total | 22/100 (22%) | Mean 22.01% SD 0.62% |
| | | | | | | | |
| *Thyroid Gland: Follicular Cell: | | | | | | | |
| Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | 1/51 (2%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total | 1/100 (1%) | Mean 0.98% SD 1.39% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

| | | Male | | | Female | | |
|--|-------|-----------|---------|-------|-----------------------|-------------|-----------|
| *Thyroid Gland: Follicular Cell: Carcinoma or Adenoma | | | | | | | |
| | | 0/50 (0%) | | | 0/49 (0%) | 1/51 (2%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 1/100 (1%) | Mean 0.98% | SD 1.39% |
| | | | | | | | |
| #Tooth: Odontoma | | | | | | | |
| | | 0/50 (0%) | | | 0/50 (0%) | 1/52 (2%) | |
| Overall Incidence | Total | 0/50 (0%) | Mean 0% | SD 0% | Total 1/102 (0.98%) | Mean 0.96% | SD 1.36% |
| | | | | | | | |
| #Uterus: Carcinoma | | | | | | | |
| | | | | | 0/50 (0%) | 2/52 (4%) | |
| Overall Incidence | | | | | Total 2/102 (1.96%) | Mean 1.92% | SD 2.72% |
| | | | | | | | |
| #Uterus: Polyp Stromal | | | | | | | |
| | | | | | 10/50 (20%) | 3/52 (6%) | |
| Overall Incidence | | | | | Total 13/102 (12.75%) | Mean 12.88% | SD 10.06% |
| | | | | | | | |
| #Uterus: Sarcoma Stromal | | | | | | | |
| | | | | | 2/50 (4%) | 0/52 (0%) | |
| Overall Incidence | | | | | Total 2/102 (1.96%) | Mean 2% | SD 2.83% |
| | | | | | | | |
| #Uterus: Sarcoma Stromal or Polyp Stromal | | | | | | | |
| | | | | | 12/50 (24%) | 3/52 (6%) | |
| Overall Incidence | | | | | Total 15/102 (14.71%) | Mean 14.88% | SD 12.89% |
| | | | | | | | |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Jun2013

Contract/Lab: All Laboratories

Species: RATS

Strain: Harlan Sprague-Dawley

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Page: 19

Report Date: 06/17/2013

| | Male | | | Female | | |
|--------------------------------|------|-------|---------------|------------|----|-------|
| #Uterus: | | | | | | |
| Schwannoma Malignant | | | | | | |
| | | | 0/50 (0%) | 1/52 (2%) | | |
| Overall Incidence | | Total | 1/102 (0.98%) | Mean 0.96% | SD | 1.36% |
| | | | | | | |
| #Vagina: | | | | | | |
| Polyp | | | | | | |
| | | | 1/50 (2%) | 1/52 (2%) | | |
| Overall Incidence | | Total | 2/102 (1.96%) | Mean 1.96% | SD | 0.05% |
| | | | | | | |
| #Vagina: | | | | | | |
| Schwannoma Malignant | | | | | | |
| | | | 1/50 (2%) | 0/52 (0%) | | |
| Overall Incidence | | Total | 1/102 (0.98%) | Mean 1% | SD | 1.41% |
| | | | | | | |
| #Vagina: | | | | | | |
| Squamous Cell Carcinoma | | | | | | |
| | | | 0/50 (0%) | 1/52 (2%) | | |
| Overall Incidence | | Total | 1/102 (0.98%) | Mean 0.96% | SD | 1.36% |

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied